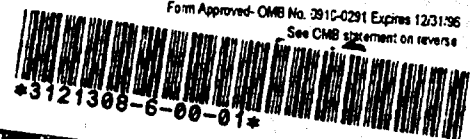


CDEF

CDER
For VOLUNTARY report
by health professionals of ad-
events and product proble

Page 1 of 1

Form Approved OMB No. 3910-0291 Expires 12/31/96
See CMB statement on reverse



A. Patient information

1. Patient Identifier In confidence	2. Age at time of event: 57 Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs 80 kgs
----------------------------------------	-----------------------------------------------	---------------------------------------------------------------------------------------	-------------------------------

B. Adverse event or product problem

1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization	<input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other:
3. Date of event (month/day/yr) 8/11/98	4. Date of this report (month/day/yr) 8-21-98
5. Describe event or problem BF was given Acetaminophen IV, and now has Grade 4 Hepatotoxicity due to high dose of acetaminophen.	

REC'D.
AUG 24 1998
MEDWATCH CTU

6. Relevant tests/laboratory data, including dates
LFTs 8-12-98 AST 855 LFTs 8-13-98 AST 1315

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
NONE

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 Acetaminophen 30, 500 mg #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 8-11-98 #2	
2. Dose, frequency & route used #1 IV #2		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
4. Diagnosis for use (indication) #1 Ocular Melanoma- Metastatic #2		8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known) #1 #2	7. Exp. date (if known) #1 #2	9. NDC # (for product problems only) - -	
10. Concomitant medical products and therapy dates (exclude treatment of event) NONE			

D. Suspect medical device

1. Brand name		4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:	
2. Type of Device		5. Expiration Date (month/day/yr)	
3. Manufacturer name & address		7. If implanted, give date (month/day/yr)	
6. model # catalog # serial # lot # other #		8. If explanted, give date (month/day/yr)	
9. Device available for evaluation? (Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (month/day/yr)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			

E. Reporter (See confidentiality section on back)

1. Name & Address [Redacted] Cancer Center [Redacted] Ave. [Redacted]		phone #
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>		

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0176

FDA Form 3500 (1/96)

MEDWATCH

HF-2

Taken By Telephone

CTI 198362